

**IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA**

APOTEX, INC.,

Plaintiff,

v.

CEPHALON, INC., et al.,

Defendants.

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CIVIL ACTION

No. 2:06-cv-2768

**LETTER ROGATORY SEEKING TO TAKE A
DEPOSITION IN THE PROVINCE OF ONTARIO, CANADA**

THE UNITED STATES DISTRICT COURT FOR THE EASTERN DISTRICT OF PENNSYLVANIA, to the appropriate judicial authorities of the Province of Ontario, Canada:

The above-captioned action is pending before me in the U.S. District Court for the Eastern District of Pennsylvania, a competent United States court of law and equity with the power to compel the attendance of witnesses both in and outside its jurisdiction. The action was filed on June 26, 2006, by Plaintiff Apotex, Inc. (“Apotex”) against Defendant Cephalon, Inc. (“Cephalon”) as well as co-defendants Barr Laboratories, Inc., Mylan Laboratories, Inc., Teva Pharmaceutical Industries, Ltd., and Ranbaxy Laboratories, Ltd. (the “Generic Defendants”). Cephalon answered the second amended complaint on March 8, 2009, and the case is now in the discovery phase.

Apotex’s claims arise out of the settlements of separate underlying litigation concerning Cephalon’s U.S. Reissue Patent No. 37,516, which covers a wakefulness promoting pharmaceutical called Provigil®. In 2003, the Generic Defendants each announced their intention to launch a generic version of Provigil®, in spite of Cephalon’s patent. In response, Cephalon brought an action

against the four Generic Defendants, alleging that their proposed launch of generic versions of Provigil® would infringe Cephalon's patent. By February 2006, Cephalon had settled that underlying patent infringement litigation with each of the four Generic Defendants. In the instant action, Apotex alleges, among other things, that those settlements violated U.S. antitrust laws. Apotex further alleges that those settlements prevented Apotex from obtaining the U.S. Food and Drug Administration's ("FDA") approval for its own generic version of Provigil®. For relief, Apotex seeks treble damages for the period of time that it claims it could have sold a generic version of Provigil® in the United States, but was prevented from doing so by the settlement agreements (the "Damages Period").

For part of the Damages Period, and through the present day, Apotex has been subject to Import Alert 66-40, imposed by the FDA, on the grounds that the methods and controls used in Apotex's manufacture and control of its pharmaceutical products do not appear to conform to current good manufacturing practices ("CGMP") within the meaning of relevant U.S. law and regulations. Import Alert 66-40 was imposed on Apotex on August 28, 2009, and remains in effect today. As a result, Apotex has stated that it is no longer seeking damages from Cephalon or the Generic Defendants for the period during which Apotex was subject to the Import Alert.

However, Cephalon believes that because the CGMP violations identified by the FDA date back as far as 2005, which is before Apotex could have sold its generic version of Provigil®, it is entitled to take discovery to determine the extent to which violations may have prevented Apotex from receiving approval from the FDA for its generic version of Provigil®; reduced the time that, had Apotex received FDA approval, Apotex's generic version of Provigil® would have been on the U.S. market; and, assuming it ever reached the U.S. market, reduced the demand for Apotex's generic version of Provigil® on the market. This information is not publicly available.

To gather relevant information on these subjects, Cephalon seeks to take the deposition of Lance Lovelock, who is believed to be a Canadian citizen and resident of the Province of Ontario. Mr. Lovelock is a former employee of Apotex, a Canadian company with headquarters located at 150 Signet Drive, Toronto, Ontario, M9L 1T9. To this end, Cephalon is seeking the aid of the appropriate judicial authorities in the Province of Ontario in obtaining Mr. Lovelock's deposition.

Cephalon properly seeks Mr. Lovelock's relevant firsthand knowledge about limitations on Apotex's ability to obtain FDA approval of its generic version of Provigil® and import that product into the United States. Mr. Lovelock served as Apotex's Vice President of Quality Assurance during the Damages Period. Bernice Tao, Apotex's current Director of Regulatory Affairs, in sworn deposition testimony, identified Mr. Lovelock as the Apotex employee who would have communicated with the FDA about Apotex's CGMP violations and FDA approval. FDA warning letters concerning the violations that formed the basis for Import Alert 66-40 were addressed to Mr. Lovelock. Mr. Lovelock was also involved in changes in generic Provigil® launch plans. Mr. Lovelock's testimony regarding Apotex's CGMP issues is relevant to the antitrust case because he has unique and specific knowledge concerning Apotex's CGMP violations and the Import Alert as it relates to Apotex's damages.

Based on the foregoing, Mr. Lovelock's testimony will aid in reaching a full and fair decision regarding the merits of Apotex's action. Any information obtained through the deposition of Mr. Lovelock will be used in conjunction with this action. Due to Mr. Lovelock's unique position at Apotex during the alleged Damages Period, the evidence that will be obtained by deposing him is most likely not available by other means. Compelling Mr. Lovelock to be deposed is neither contrary to public policy, nor will it be unduly burdensome.

This Court therefore requests, in accordance with the Ontario Evidence Act, and/or any other

applicable procedure, that the appropriate judicial authorities compel Mr. Lovelock, who resides within your jurisdiction, at 941 Red Deer Avenue, Oshawa, Ontario L1K 0C4, to appear for examination under oath by counsel for Defendants in the present matter, at a time and place to be determined by the appropriate judicial authority in Ontario, but no later than April 15, 2011, on the issue of Apotex's CGMP violations related to Apotex's generic version of Provigil®, and that the deposition be recorded by an official stenographer within your jurisdiction.



Honorable Mitchell S. Goldberg
United States District Judge